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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,771	09/26/2003	Richard David Guarino	P-5840P1	4333
47656	7590	02/27/2006		
BECTON, DICKINSON AND COMPANY ALSTON & BIRD LLP 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			EXAMINER TSAY, MARSHA M	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 02/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,771

Applicant(s)

GUARINO ET AL.

Examiner

Marsha M. Tsay

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30,31,38 and 65-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,38 and 65-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/23/05</u> . | 6) <input type="checkbox"/> Other: _____ |

This Office Action is in response to Applicants' amendment received November 23, 2005. Claims 1-29, 32-37, 39-64 are canceled. Claims 30-31, 38, 65-85 are pending and under examination.

Priority date is August 13, 2004.

Withdrawal of Objections and Rejections

The rejection of claims 1, 29-30 under 35 U.S.C. 102(b) as being anticipated by Glass et al. (1996 Biomaterials 17: 1101-1108) is withdrawn.

The rejection of claims 1, 29-31, 65-66 under 35 U.S.C. 102(b) as being anticipated by Mayes et al. (US 6150459) is withdrawn.

The rejection of claims 1, 29-31, 38 under 35 U.S.C. 102(b) as being anticipated by Brandley et al. (1988 Analytical Chemistry 172: 270-278) is withdrawn.

The rejection of claims 1, 29-31 under 35 U.S.C. 102(e) as being anticipated by Campbell et al. (US 20030162289 A1) is withdrawn.

New Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30, 30-31, 38, 65-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (US 20030162289 A1; previous PTO-892) in view of Glass et al. (1996 Biomaterials 17: 1101-1108; previous PTO-892). Campbell et al. teach pentapeptides promoting cell adherence, growth and secretion that may be non-specifically adsorbed, or chemically attached to a surface or formulated in a culture medium to produce the desired effect on cultured cells (p. 2 [0021]). Campbell et al. also disclose suitable surfaces include polymer surfaces such as poly(hydroxyethylmethacrylate), poly(ethylene terephthalate), poly(tetrafluoroethylene), fluorinated ethylene, poly(dimethyl siloxane), silicon rubbers, glass surfaces, plastic surfaces, and ceramics. In examples 1-5, Campbell et al. teach peptides affecting cell adherence and growth for the cell line MC3T3-E1, a clonal line of murine calvaria-derived osteoblast cells (p. 8, [0080]; claim 1, 29-31). Campbell et al. teach cell maintenance in example 2 and the monitoring of cell growth in example 4 (p. 8). Growth was monitored at the following time points: 1 hour, 24 hours, 32 hours, 48 hours and 86 hours. Media was changed every three days (p. 9). In Figure 1 and Table 1, Campbell et al. show the inventive peptides promote the growth of MC3T3 cells wherein the peptide controls, polylysine and RGDSP, do not (p. 9, [0100]). Campbell et al. do not teach a hyaluronic acid (HA) layer bonded to the polymer surface.

Glass et al. teach methods to covalently couple RGD-containing peptides to a cross-linked natural biopolymer, hyaluronic acid (HA) and the characterization of this peptide cell attachment matrix (p. 1101; claim 1). Glass et al. teach samples containing the HA-peptide cell matrix are used in a cell attachment assay for MG63 human

Art Unit: 1653

osteosarcoma cells. At the end of the assay, the samples are transferred to 24-well dishes and non-bound cells removed by washing three times with phosphate-buffered saline (p. 1102; claim 30). For long-term growth of cells, the matrices containing attached cells were placed in DMEM containing 10% defined bovine serum and maintained at 37°C for 5 days (p. 1102; claim 30).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to develop a method for growing adherent cells, such as osteoblasts, comprising providing a composition comprising a polymer surface, a HA layer bonded to the polymer surface, and one or more pentapeptides that lack a RGD sequence covalently bound to the HA layer, followed by the addition of osteoblasts and allowing sufficient incubation time for the osteoblasts to adhere to the polymer surface (claims 30-31, 38, 67-68, 79, 81) because Campbell et al. teach a series of pentapeptides that lack the RGD sequence wherein the pentapeptides promote cell adherence and growth on different types of surfaces including polymer surfaces and Glass et al. teach a peptide-cell attachment matrix comprising hyaluronic acid (HA) can be used as a polymer surface for the successful adherence and growth of cells. It would also have been obvious to a person having ordinary skill in the art to know and understand that the pentapeptides of Campbell et al. can be used to promote adherence and growth to other mammalian cells are not limited to osteoblasts (claims 65-66, 69-78, 80, 82-85).

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

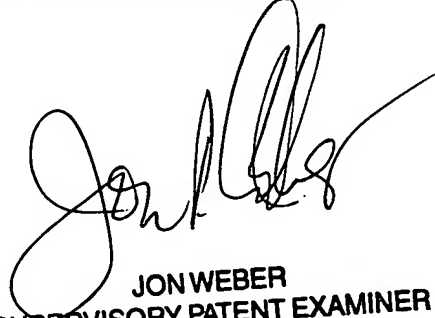
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 21, 2006



JON WEBER
SUPERVISORY PATENT EXAMINER